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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,645	03/25/2004	Debleena Dey	KSP-1001US	7493

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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,645	DEY ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *9-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, Claims 1-8, in the reply filed on December 12, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-8 are under examination.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawing are either so dark or so the lines of the drawings are so blurred that it is not possible to ascertain the details of the drawings. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *in vitro* method of treating and/or reducing the risk of development of type II diabetes, said method comprising a step of administering a pharmaceutically effective amount of a root extract of plant *Pueraria tuberosa* or butanol fraction of the extract or Lupinoside A4 (LPA_4), optionally along with additive(s) to cells, does not reasonably provide enablement for preventing type II diabetes in a subject in need thereof comprising the administration of any and all extracts of the claim-designated plant to a subject in need thereof, and wherein the subject is either an animal or a human being. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as broadly claimed.

The claims are drawn to a method of preventing and/or treating diabetes type II in a subject in need thereof, said method comprising a step of administering a pharmaceutically effective amount of an extract of plant *Pueraria tuberosa* or butanol fraction of the extract or Lupinoside A4 (LPA_4), optionally along with additive(s) to the subject. Dependent claims are drawn to a method as claimed in claim 1, wherein the subject is an animal; wherein the subject is a human being; wherein the extract is obtained from rot of the plant; wherein the additive is selected from a group comprising nutrients such as proteins, carbohydrates, sugars, talc, magnesium stearate, cellulose, calcium carbonate, starch, gelatin paste, pharmaceutically carrier, excipients, diluent, and solvent; wherein the fraction is administered at a concentration ranging between 1 to 40 mg/kg body weight; wherein the Lupinoside is administered at a concentration

ranging between 1 to 40 mg/kg body weight; and, wherein the administration route is selected from a group comprising orally, intravenously, intramuscularly, and subcutaneously.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

While the specification does reasonably demonstrate *in vitro* method of treating and/or reducing the risk of development of type II diabetes, said method comprising a step of administering a pharmaceutically effective amount of a root extract of plant *Pueraria tuberosa* or butanol fraction of the extract or Lupinoside A4 (LPA_4), optionally along with additive(s) to a cell culture, the specification does not demonstrate a method for preventing and/or treating diabetes in a subject in need thereof comprising administering therapeutically effective amounts of a root extract of plant *Pueraria tuberosa* or butanol fraction of the extract or Lupinoside A4 (LPA_4), optionally along with additive(s) or any and all extracts obtained from the claim-designated plant wherein the extract is prepared using any and all parts of the plant and wherein the extract is prepared using any and all solvents, wherein the subject is either an animal or a human

being, and wherein in the administration is by any and all routes of administration, as broadly claimed. For example, on page 11, line 14 to page 18, line 3, Applicant reasonably discloses an *in vitro* method for treating diabetes type II by demonstrating that effective amounts of LP4 prevents palmitate induced defects on insulin signaling 3T3L1 adipocyte cells and that effective amounts of LP4 allow insulin to stimulate IR-beta and Akt phosphorylation in the cells. While the data obtained from Applicant's methods of incubating palmitate-treated 3T3L1 cells with effective dose amounts of LPA4, a butanol fraction of an extract from the root of *Pueraria tuberosa* prevented palmitate-induced defects on insulin signaling by allowing insulin to stimulate Irß and Akt phosphorylation, and insulin-induced Glut translocation, the Office notes that Applicant has not demonstrated a method for the administration of pharmaceutically effective amounts of any and all extracts of the claim-designated plant, wherein the extract is prepared from any and all parts of the claim-designated plant and/or any and all solvents, and wherein the administration is to either an animal or a human being, and wherein the administration is by any and all administration routes to provide a method of preventing and/or treating diabetes type II in the animal or the human being.

Claims drawn to pharmaceutically acceptable compositions and methods of administering compounds to living subjects which would in effect 'prevent' the condition from happening require supporting evidence which clearly define the ingredients or constituents therein and supporting data because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis. In order to enable the skilled artisan to practice the invention as claimed, Applicant would have to demonstrate

the functional effect and describe the therapeutic effect or prophylactic effect, and describe the effective amounts of each ingredient for the administration of the composition intended for a therapeutic treatment or prophylaxis. Nowhere in the specification as originally filed has Applicant provided any data demonstrating a method for preventing and/or treating diabetes type II in either a human or an animal comprising the administration of pharmaceutically effective amounts of either the disclosed butanol fraction of the claim-designated plant or LPA4 thereof, much less any and all extracts of the claim-designated plant, wherein the extract is prepared from any and all parts of the claim-designated plant and any and all solvents, and wherein the administration is to either an animal or a human being, and wherein the administration is by any and all administration routes to provide a method of preventing and/or treating diabetes type II in the animal or the human being.

Moreover, the state of the art at the time the invention was filed did not recognize methods for the prevention of Type II diabetes comprising the administration of pharmaceuticals *per se*, as evidenced by Davies M J et al. (Diabetic Medicine (5/2004), 21(5): 403-414. *"Prevention of Type 2 Diabetes Mellitus. A review of the evidence and its application in a UK setting"*). For instance, Davies teaches Type II diabetes as a complex, metabolic, multifactorial disease wherein the evidence for the prevention of diabetes is for interventions that target individuals at highest risk. Davies teaches lifestyle interventions, *e.g.,* increased physical activity and decreasing body fat stores, thereby decreasing body weight, decrease the progression of impaired glucose tolerance to diabetes. Davies also teaches administering either traditional or newer

pharmacological agents may alter glucose tolerance or reduce the risk of the progression of diabetes. However, Davies does not indicate that there are any known methods to prevent Type II diabetes. In fact, Davies suggests that the administration of pharmacological agents purported to "prevent" diabetes warrant further investigation. For instance, on page 408, Column 1, under *"Acarbose",* Davies discloses that the administration of acarbose to humans produced a 25% relative risk reduction in progression to diabetes compared with placebo. Davies further discloses, "When acarbose was stopped, there was an increase in the incidence of diabetes, suggesting that the benefit of acarbose is only present for as long as it is taken." *See* also Sturis, J et al., American J of Physiology (1995), 269(4Pt 1): E786-92. "*Prevention of diabetes does not completely prevent insulin secretion defects in the ZDF rat*", which discloses "Treatment with acarbose before or with pioglitazone after diabetes onset improved but did not normalize glucose levels, and it did not improve entrainment." Like the acarbose study, the administration of the claim-designated plant extract used in the instantly claimed method disclosed by Applicant results in maintenance of normal glycemia until withdrawal of therapy. Thus, while on page 74, Column 2, lines 34-40 (Friedman, J. E. et al. American Journal of Physiology (1991), 261(6): 74-80. Altered expression of muscle glucose transporter GLUT-4 in diabetic fatty Zucker rats (ZDF/Drt-fa) Friedman et al. teaches, "Our findings indicate that, there is a downregulation of muscle GLUT-4 expression in red but not white muscle fiber types and that early administration of acarbose to prediabetic rats reduce hyperglycemia, increase ß-cell responsiveness, and prevents the loss of GLUT-4 expression in skeletal muscle.", the teachings of Davies

and Sturgis suggest that the administration of acarbose having similar functional properties as the plant extracts or fractions thereof disclosed by Applicant fails to prevent diabetes type II in humans by preserving ß-cell responsiveness and Glut-4 expression. Furthermore, at the time the invention was filed, Shukla (Shukla. Sangeeta. International Journal of Pharmacognosy (1995), 33(4): 324-329. Toxicological Studies of *Pueraria tuberosa*, a potent antifertility plant.) taught administering dose amounts, which were the same dose amounts disclosed by Applicant as being therapeutically effective amounts to provide an anti-diabetic effects in animals, of a butanol extract obtained from the tuber of the claim-designated plant did not alter the level of blood sugar in the treated animals. Yet, Applicant broadly claims that the administration of the claim-designated plant extracts to either animals or human beings is effective in the prevention Type II diabetes. Please note that the instant application does not provide a working example providing data that shows that the claim-designated compositions of the instant claims would indeed prevent or eliminate the claim-designated disease condition. Thus, Applicant has not demonstrated a method for preventing Type II diabetes in either an animal or a human in need thereof comprising the administration of the claim-designated ingredients, as broadly claimed, other than the aforementioned and demonstrated treatment of non-insulin dependent type II diabetes comprising the administration of effective amounts of the claim-designated plant extracts to a subject to provide an in vitro method of treating and/or preventing diabetes type II.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one skill in the art to provide a method of preventing and/or

treating diabetes type II comprising administering a pharmaceutically effective amount of an extract of plant *Pueraria tuberosa* to any and all subjects, and wherein the extract is from any and all parts of the claim-designated plant and any and all solvents, wherein the administration is to either an animal or a human being, and wherein the administration is by any and all administration routes to provide a method of preventing and/or treating diabetes type II in a subject, as broadly claimed by Applicant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art). For example, is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its

ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the step(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

Claims 6 and 7 recite the limitation "the concentration range" in lines 1-2. There is insufficient antecedent basis for this limitation in the claims. Applicant may overcome the rejection by replacing "the" with a.

Claim 8 recites the limitation "the administration route" in line 1. There is insufficient antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

With regard to Claim 1, line 3, there is an apparent misspelling. Applicant may overcome the objection by replacing "*Pureria tuberosa*" with *Pueraria tuberosa*.

With regard to Claim 1, line 2 there is an apparent omission of an article. Applicant may overcome the objection by adding a, before "step".

With regard to Claim 1, line 2 there is an apparent omission of an article. Applicant may overcome the objection by adding a, before "pharmaceutically".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
February 21, 2006